REMARKS

Claims 1-3, 5-12 and 21-25 were examined. Applicants amend no claims and submit no additional claims.

Applicants note with appreciation that claim 25 is allowable if rewritten in independent form. The Patent Office rejects claims 1-3, 6, 8, 11, 12 and 21-24 under 35 U.S.C. §102(e) and claims 5, 7, 9 and 10 under 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the above amendment and the following remarks.

A. Claim Objections

The Patent Office Objects to the claims because of a typographical error and requests that misnumbered "newly added" claim 24 be renumbered as claim 25. Applicants have renumbered the claim as suggested.

B. <u>Double Patenting Rejection</u>

All the claims are rejected under nonstatutory double patenting in view of claims 1-4 of U.S. Patent No. 7,364,567. In response, Applicants submit the attached Terminal Disclaimer.

C. 35 U.S.C. §102 and §103: Rejection of the Claims

The Patent Office rejects claims 1-3, 6, 8, 11, 12 and 21-24 under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,248,112 to Gambale et al. ("Gamabale"). The Patent Office rejects claims 5, 7, 9, and 10 under 35 U.S.C. §103(a) as being unpatentable over Gambale.

Applicants submit that independent claim 1 is not disclosed by or taught by Gambale for at least the reason that Gambale does not disclose or teach a needle with a first opening to a lumen of the needle and a second opening to the <u>same</u> lumen of the needle, and a fluid pressure measurement to measure a second pressure when the first opening becomes occluded, and a third pressure when an aperture of the second opening becomes occluded, as required by claim 1.

Gambale teaches multiple pressure ports spaced along a distal end of a device, where each port is monitored though <u>individual lumens</u> extending through the tube and in communication with monitoring device 31 (see column 7, line 66 through column 8, line 5).

Consequently, Gambale does not teach a first and second opening to the same lumen, so that a second pressure can be measured when the first opening becomes occluded, and a third pressure can be measured when an aperture of the second opening becomes occluded, as required by claim 1.

Moreover, it can be appreciated that by having both openings in the same lumen of the needle, embodiments described in the application, for example, without limitation thereto provide at least the benefit of using a single lumen to inject a therapeutic agent and to sense penetration depth during injection, by injecting the agent into tissue using the second opening while measuring the second pressure of the fluid being injected to sense that the first opening is occluded due to penetration (e.g. see at least claims 1, 3, 6 and 11; and paragraphs 30-32 and 35; and Figs. 1-3B of the application). On the other hand, this is not taught or possible in Gambale.

In addition to being dependent upon allowable base claims, Applicants disagree with the rejection of the dependent claims for at least the reason noted above.

Hence, for at least the reasons noted above, Applicants respectfully request the Patent office withdraw all of the rejections of the claims.

D. Allowable Claim 25

Applicants note with appreciation the Patent Office's indication that claim 25 is allowable if rewritten in independent form.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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Date: 2009-18-07

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I hereby certify that this correspondence is being submitted electronically via EFS, Web on the date shown below to the United States Patent and

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essica Huester

Date